



UNITED STATES PATENT AND TRADEMARK OFFICE

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Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
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Estelle J. Tsevdos
Kenyon & Kenyon
One Broadway
New York, NY 10004

Re: Patent Term Extension
Application for
U.S. Patent No. 5,360,897

An order granting an interim extension under 35 U.S.C. § 156(e)(2) is enclosed extending the term of U.S. Patent No. 5,360,897 for a period of 1,086 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket *95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website:
<http://www.fda.gov/opacom/morechoices/fdaforms/default.html>
(<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at (571)272-7744, or at Karin.Ferriter@uspto.gov by e-mail.

Karin Ferriter
Karin Ferriter
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 13
5600 Fishers Lane,
Rockville, MD 20857

Attention: Claudia Grillo

RE: PREVNAR®
FDA Docket No.: 00E-1403

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(12)

CERTIFICATE EXTENDING PATENT TERM
UNDER 35 U.S.C. § 156

(68) PATENT NO. : 5,360,897
(45) ISSUED : November 1, 1994
(75) INVENTOR : Porter W. Anderson, et al.
(73) PATENT OWNER : The University of Rochester
(95) PRODUCT : PREVNAR® vaccine (Diphtheria CRM₁₉₇ Protein)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 5,360,897 based upon the regulatory review of the product PREVNAR® by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 1,086 days

from June 16, 2004, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this 16th day of September 2004.


Jon W. Dudas
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office